NOT FOR PUBLICATION

IN RE: FOSAMAX (ALENDRONATE SODIUM) PRODUCTS LIABILITY LITIGATION (NO. II)	MDL No. 2243 (JAP-LHG)
RELATES TO ALL ACTIONS	**MEMORANDUM OPINION**

PISANO, Judge

Presently before the Court is Defendants' Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively "Watson") Motion for Judgment on the Pleadings seeking dismissal from this MDL pursuant to the Supreme Court's decision in *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011). (DE 250.) Plaintiffs opposed the motion. (DE 296.) On January 12, 2012, the Court held oral argument on Watson's motion. For the reasons that follow, the Court will grant the motion and dismiss Watson from the case.

I. BACKGROUND

The MDL is a series of products liability suits concerning Fosamax, a drug prescribed for the treatment and prevention of osteoporosis and Paget's disease. Plaintiffs in these cases brought claims in various courts and venues against both the manufacturer of Fosamax, Merck & Co., Inc. ("Merck"), and against manufacturers of generic Fosamax. Plaintiffs' claims emanated from a general theory of failure to warn, but also included claims based upon various state law products liability theories, including, *inter alia*, defective design, negligence, fraud, misrepresentation, breach of express and implied warranties, violation of consumer protection statutes, restitution, and loss of consortium. On May 25, 2011, the United States Judicial Panel

on Multidistrict Litigation centralized all actions for coordinated and consolidated pretrial proceedings in the District of New Jersey. (DE 30.)

Watson is named as a defendant in seven (7) cases currently pending in this MDL.[1] In one of those cases, *Welch v. Merck, Sharp & Dohme Corp et al.* ("*Welch*"), Plaintiffs named Watson to the group of "Generic Defendants" who they allege manufactured, promoted, and sold generic Fosamax (alendronate sodium). (*Welch* Compl. ¶¶ 15, 18.) In a later paragraph, however, the *Welch* complaint states the following: "Defendant Watson was what is known as the authorized distributor of branded Fosamax. Upon information and belief, under the agreement between Merck and Watson, Merck manufactured and supplied alendronate and Watson marketed and sold the drug under branded name Fosamax." (Welch Compl. ¶ 109.) None of the other six complaints naming Watson as a defendant make this allegation.

On October 3, 2011, Defendants Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals, LLC, Barr Laboratories, Inc., Mylan, Inc., Mylan Pharmaceuticals, Inc., Apotex Corporation, Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharmaceuticals Inc. on behalf of and formally known as Cobalt Pharmaceuticals Company, and Sun Pharmaceuticals (collectively, the "Generic Defendants") filed a motion for judgment on the pleadings, arguing that Plaintiffs' claims were preempted based upon the Supreme Court's recent decision in *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011). Plaintiffs opposed the motion.

On November 14, 2011, Chief Judge Garrett E. Brown denied Watson's motion for judgment on the pleadings. (*See* DE 344, 345.) That decision was based on the statement in the *Welch* complaint that alleged that Watson was an authorized distributor of branded Fosamax.

[1] *Eastwood v. Merck, Sharp & Dohme Corp.*, 3:11-cv-05188; *Marks v. Merck & Co, Inc.*, 3:11-cv-05079; *Hardy v. Merck & Co, Inc.*, 3:11-cv-5077; *Murphy v. Merck & Co. Inc.*, 3:11-cv-5082; *Naccio v. Merck, Sharp & Dohme Corp.*, 3:11-cv-4055; *Brown v. Merck & Co. Inc.*, 3:11-cv-3867; and *Welch v. Merck, Sharp & Dohme Corp.*, 3:11-cv-03045.

Chief Judge Brown found that he could not "rule as a matter of law that Watson is a generic" manufacturer because he was required to take the Plaintiffs' allegations as true for purposes of the motion. (11/14/11 tr. 12: 25–13:2.)

On November 28, 2011, Watson moved for reconsideration and clarification of Chief Judge Brown's decision. On December 23, 2011, the Court granted in part Watson's Motion for Reconsideration and Clarification as it related to the denial of Watson's motion for judgment on the pleadings, and the Court vacated the Order entered on November 14, 2011 to the extent it denied Watson's motion for judgment on the pleadings. The Court reopened the record for oral argument on January 12, 2012.

II. STANDARD OF REVIEW

Rule 12(c) of the Federal Rules of Civil Procedure allows a party to move for judgment on the pleadings "after the pleadings are closed but within such time as not to delay trial . . ." Fed. R. Civ. P. 12(c). The applicable standard on a motion for judgment on the pleadings is materially the same standard applied on a motion to dismiss pursuant to Rule 12(b)(6). *Spruill v. Gillis*, 372 F.3d 218, 223 n.2 (3d Cir. 2004). In reviewing a motion made pursuant to Rule 12(c), a court must take all allegations in the complaint as true, viewed in the light most favorable to the plaintiff. *Gomez v. Toledo*, 446 U.S. 635, 636 n.3, (1980); *Robb v. City of Philadelphia*, 733 F.2d 286, 287 (3d Cir. 1984). Under Rule 12(c), "judgment will not be granted unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." *Jablonski v. Pan American World Airways, Inc*., 863 F.2d 289, 290 (3d Cir. 1988) (citation omitted).

III. DISCUSSION

Watson asserts that it is entitled to judgment on the pleadings because Plaintiffs' state tort claims are preempted by federal law. The Supremacy Clause states that federal law "shall be the supreme Law of the Land . . . and any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Implied preemption, the type of preemption at issue in this motion, occurs when it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995). In other words, when state law requires what federal law forbids, state law must give way. *See Wyeth v. Levine*, 555 U.S. 555, 583 (2009).

In *PLIVA v. Mensing*, the Supreme Court ruled plaintiffs' state failure-to-warn claims against several generic manufacturers of the drug metoclopramide were preempted by the federal Food, Drug and Cosmetic Act (FDCA). *Mensing*, 131 S. Ct. at 2573. The state tort laws applicable in the case required manufacturers that are "or should be aware of [their] product's danger to label that product in a way that renders it reasonably safe." *Id.* at 2573. But the Court found that generic manufacturers have, under the FDCA, a federal duty of "sameness" to ensure that the label for the generic drug is identical to the label adorning the corresponding branded or reference-listed drug. *Id.* at 2575. Generic manufacturers have no means for unilaterally changing the labeling of their generic products. *Id.* Changes of generic labeling required action by either the reference-listed drug manufacturer and/or the FDA. *Id.* at 2576-78.

Accordingly, the Court held "that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 2581. As a result, the *Mensing* plaintiffs' state failure-to-warn claims were

preempted "because it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." *Id.* at 2587.

The *Mensing* decision, however, does not apply to brand manufacturers. In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Supreme Court held that a patient's state law failure-to-warn claim against a brand drug manufacturer is *not* preempted by federal law. Unlike a generic manufacturer, a brand manufacturer may "unilaterally strengthen its warning." *Id.* at 573. Consequently, a brand manufacturer can simultaneously comply with both state and federal law.

Here, it is important to highlight the distinction created by the Supreme Court between generic and brand manufacturers. Watson claims it is a generic manufacturer, requiring its dismissal under *Mensing*. But Plaintiffs assert that Watson is not a generic manufacturer because it contracted with Merck to distribute branded Fosamax. As a result, Plaintiffs allege that Watson stands in the shoes of Merck and has the ability to change the Fosamax labeling. If this is the case, *Wyeth* applies to prevent Watson's dismissal from the MDL.

Plaintiffs' argument fails as a matter of law for two reasons. First, the Plaintiffs in *Naccio*, *Brown*, *Hardy*, *Murphy*, *Marks*, and *Eastwood* do not allege that there was an agreement between Watson and Merck that allowed Watson to distribute branded Fosamax. In other words, those Plaintiffs did not make the claim that formed the basis of the November 14, 2011 decision to deny Watson's motion to dismiss. Therefore, Watson is entitled to dismissal from those cases because, as a generic manufacturer, the Plaintiffs' state law claims against Watson are preempted under *Mensing*.

Second, even if the Plaintiffs in the *Naccio*, *Brown*, *Hardy*, *Murphy*, *Marks*, and *Eastwood* cases made the allegation found in *Welch*—that Watson was an authorized distributor of Fosamax—Watson would still be entitled to judgment on the pleadings and dismissal from the

MDL. As a distributor of Fosamax, Watson has no power to change Fosamax labeling. That power lies with the applicant who filed the New Drug Application (NDA) seeking approval to market Fosamax. *See* 21 U.S.C. 355(b); 21 C.F.R. 314.70 (describing the Changes Being Effected or "CBE" regulation, which requires that "the *applicant* must notify FDA about each change in each condition established in an approved application.") (emphasis added). In this case, Merck is the NDA applicant with the corresponding authority to change labeling. Additionally, if FDA had "become aware of new safety information" in connection with Fosamax use that "it believe[d] should be included in the labeling," FDA must notify the holder of the NDA to initiate the changes. 21 U.S.C. 355(o)(4)(A). Neither of these procedures involves a distributor.

As a result of the scheme set forth by the FDCA, Watson has no authority to initiate a labeling change of Fosamax. That authority lies with the FDA and/or with Merck. Even taking the allegation in *Welch* as true, a contractual relationship between Watson and Merck cannot change the fact that Watson is not the NDA holder. Consequently, Watson has no power to unilaterally change Fosamax labeling. Because Watson could not "independently do under federal law what state law requires of it," the state law claims brought against it are preempted. *Mensing*, 131 S. Ct. at 2579.

III. CONCLUSION

For the reasons above, Watson's motion for judgment on the pleadings is granted. An appropriate Order will follow.

Date: January 17, 2012

/S/ JOEL A. PISANO
United States District Judge